Research Ethics and Governance 2023-24 Fee Schedule

Fees are applicable from 1 January 2023

The below fee schedule relates to the review of items submitted for ethics and site governance review. An invoice will be issued on receipt of submission.

New Research Projects/Applications:

(All fees include GST)
Where applicable to the submitter's organisation, Purchase Order Numbers ***must be provided*** *with submission*

(Note: No fee for review of student projects below the level of PhD)

1	CTN Scheme Application with a Commercial/Pharmaceutical Sponsor Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$6000
2	CTA/CTE Scheme Applications Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$6000
3a	Pharmaceutical sponsor – sub-studies or extensions Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for Extension Study	$3000
3b	Pharmaceutical sponsor – registry study Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for Registry Study	$3000
4	Clinical Trials supported by, but not instigated by, a Pharmaceutical Company Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$1100
5	Research Projects funded by Grants Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$200
6	PhD Projects Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$200
7	Application for Clinical Trial with sponsorship from collaborative groups Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$300
8	Single-site, investigator-initiated study where the Principal Investigator is based at one of the affiliated institutions (Australian National University, University of Canberra, Australian Catholic University or ACT Health) Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$200
9	Single-site, investigator-initiated study where the Principal Investigator is neither a student/employee of ACT Health nor one of the affiliated institutions listed above. Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$200
10a	Therapeutic Goods Administration (TGA) Authorised Prescriber Application (up to 5 prescribers)	$80
10b	Therapeutic Goods Administration (TGA) Authorised Prescriber Application (6 – 10 prescribers)	$120
10c	Therapeutic Goods Administration (TGA) Authorised Prescriber Application (11 or more prescribers)	Contact Secretariat office

Amendments to Existing Projects (Commercially funded)		
11	Protocol amendments[1] Description: see below	$1000
12	Investigator Brochure and other amendments[2] Description: see below	$500
13	Minor amendments[3] Description: see below	$300

[1]Major Amendments include:

- All protocol amendments, including but not limited to:
  - Revision of the study design due to safety issues
  - Revision of drug dosage, participant groups and numbers of study participants
  - Revision or correction of language, grammar and numbering in a protocol

[2]IB and Other Amendments include, but are limited to:

- Investigator Brochure updates
- Participant Information Sheet amendments (eg changes to content with ethical significance requiring HREC review)
- New Recruitment Material (eg Flyers, Advertisements, Invitation Letters, Newsletters where content requires HREC review)
- Other letters (where content needs HREC review and approval)

[3]Minor Amendments include, but are not limited to:

- Minor Participant Information Sheet amendments (eg minor wording changes with no ethical significance)
- Review of Patient Cards, updates to existing recruitment material (eg Flyers, Advertisements, Invitation Letters, Newsletters)
- Retention items (eg tote bags, magnets, pens)

Low Risk Review Pathway (no fee for student projects below the level of PhD)

14	Low Risk Project: Where the Principal Investigator is based at ACT Health or one of its affiliated institutions (Australian National University, University of Canberra, Australian Catholic University) Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$60
15	Low Risk Project: Where the Principal Investigator is a PhD student.	$60
16	Low Risk Project: External Studies– This applies to external non- affiliated university department applications where the principal investigator is neither a student/employee of ACT Health nor one of the affiliated institutions listed above. Description: Ethical Review (including transfer of lead HREC responsibility) and/or Site Specific Assessment (SSA) for New Study	$80

Please note: Commercially funded projects are ***NOT*** considered low risk

Method of Payment

EFT/Direct Debit:

Bank: Westpac Bank
Account Name: ACT Health Ethics Committee Trust
BSB: 032-777
Account Number: 002175
Description: Quote the Invoice #

PLEASE FORWARD REMITTANCE ADVICE TO THE ethics@act.gov.au

For further advice/information call the office on 02 5124 3949